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RANDOMIZED TRIAL

Early *Versus* Late Initiation of Rehabilitation After Lumbar Spinal Fusion

Economic Evaluation Alongside a Randomized Controlled Trial

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Study Design. Economic evaluation conducted alongside a randomized controlled trial with 1-year follow-up.

Objective. To examine the cost-effectiveness of initiating rehabilitation 6 weeks after surgery as opposed to 12 weeks after surgery.

Summary of Background Data. In a previously reported randomized controlled trial, we assessed the impact of timing of rehabilitation after a lumbar spinal fusion and found that a fast-track strategy led to poorer functional ability. Before making recommendations, it seems relevant to address the societal perspective including return to work, quality of life, and costs.

Methods. A cost-effectiveness analysis and a cost-utility analysis were conducted. Eighty-two patients undergoing instrumented lumbar spinal fusion due to degenerative disc disease or spondylolisthesis (grade I or II) were randomized to an identical protocol of 4 sessions of group-based rehabilitation and were instructed in home exercises focusing on active stability training. Outcome parameters included functional disability (Oswestry Disability Index) and quality-adjusted life years. Health care and productivity costs were estimated from national registries and reported in euros. Costs and effects were transformed into net benefit. Bootstrapping was used to estimate 95% confidence intervals (95% CI).

Results. The fast-track strategy tended to be costlier by €6869 (95% CI, −4640 to 18,378) while at the same time leading to significantly poorer outcomes of functional disability by −9 points (95% CI, −18 to −3) and a tendency for a reduced gain in quality-adjusted life years by −0.04 (95% CI, −0.13 to 0.01). The overall probability for the fast-track strategy being cost-effective does not reach 10% at conventional thresholds for cost-effectiveness.

Conclusion. Initiating rehabilitation at 6 weeks as opposed to 12 weeks after surgery is on average more costly and less effective. The uncertainty of this result did not seem to be sensitive to methodological issues, and clinical managements who have already adapted fast-track rehabilitation strategies have reason to reconsider their choice.

Key words: lumbar spinal fusion, rehabilitation, economic evaluation, cost-effectiveness, cost-utility, fast-track intervention, physiotherapy, occupational therapy, quality of life, randomized controlled trial.

Level of Evidence: 2

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The effect of postoperative rehabilitation after lumbar spinal fusion has been established in several studies.[1–4] The cost-effectiveness of alternative rehabilitation strategies for patients undergoing lumbar spinal fusion has only been examined in a single study. This study demonstrated that group-based rehabilitation with a broad biopsychosocial focus was cost-effective compared with not only simple video instruction, but also compared with professionally guided, intensive physiotherapy.[5]

The timing of rehabilitation *per se* may also influence the treatment outcome. In a previous study, we found that the standard practice of initiating rehabilitation 12 weeks after surgery was associated with better outcomes than a fast-track strategy of rehabilitation initiation 6 weeks after surgery.[6] Nevertheless, a successful but protracted rehabilitation may be less cost-effective because, essentially, it takes longer before the patients are considered to be fully recovered, and thus recommended to return to work. Additionally, the quality of life may be compromised for an unnecessarily lengthy time.

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The aim of this study was to examine the cost-effectiveness and cost-utility of initiating rehabilitation 6 weeks after surgery (6w-group) as opposed to 12 weeks after surgery (12w-group) from a societal perspective.

MATERIALS AND METHODS

Study Design and Intervention

This study was conducted alongside a randomized controlled trial. All patients were planned for an instrumented lumbar spinal fusion due to degenerative disc disease or spondylolisthesis grade I or II. Exclusion criteria were age below 18 years or above 64 years, a driving distance of more than 100 km to the hospital, and inability to speak and understand Danish.

Patients were included from January 2008 to January 2010 across 3 spine centers. Upon invitation to participate, they received written and verbal information about the study and signed an informed consent form. The patients were block-randomized by use of sealed envelopes at the spine center from which they were recruited. A person who did not participate in the treatment underwent the randomization procedure. The conditions of the study allowed no blinding of the therapists, the surgeons, or the patients. A total of 109 of 290 assessed patients met the inclusion criteria. Among these, 27 patients declined to participate. This left a study sample of 92 patients who were equally distributed between the 2 groups. Five patients in each group were subsequently excluded from the study: 3 patients in each group because of a noninstrumented fusion and 2 in each group because of cancellation of the surgery for reasons not being associated with the study.

Both treatment arms received exactly the same protocol, but were only initiated at different time points after surgery. Patients met with the surgeon 6 weeks (6w-group) or 12 weeks (12w-group) after surgery to discuss their postsurgery condition, based on radiographical images of their lumbar spine. Rehabilitation commenced after this meeting. Training sessions were set up at the rehabilitation units and undertaken in groups of 3 to 6 persons. The protocol was inspired by a study of Christensen *et al*,[2] which comprised 4 two-hour sessions and described in detail elsewhere.[6]

The study was approved by the Danish Data Protection Agency: 2007-41-1607 and by the Ethical Committee 2007-0264.

Costing

A societal viewpoint was taken to estimate the costs of all activity and resource use related to the patients' rehabilitation. The date of surgery was counted as "the start of the time" window that ended at the date for 1-year follow-up. Costs were reported in euros for the price year 2011.

The cost of rehabilitation was included in the tariff for surgery according to this diagnosis-related-grouping tariff. The costs of other hospital-based service utilization and the associated diagnosis-related-grouping tariff were extracted from the National Patient Registry. The number of bed days describes the inpatient hospital stay during the entire follow-up period.

TABLE 1. Baseline Characteristics of the Study Population

	6w-Group (n = 41)	12w-Group (n = 41)
Age (mean and SD)	52.0 (SD, 8.5)	51.3 (SD, 9.9)
Male	53 (21)	42 (17)
Body mass index (mean and SD)	28 (5)	28 (4)
Occupational status		
Workforce (sick listed)	64 (26)	61 (25)
Social security	7 (3)	7 (3)
Early retirement	5 (2)	12 (5)
Disability pension	24 (10)	20 (8)
Diagnosis		
Isthmic spondylolisthesis grade I-II	12 (5)	15 (6)
Degenerative disc disease	88 (36)	85 (35)
Surgical procedures		
Posterior lumbar fusion	76 (31)	85 (35)
Transforaminal lumbar interbody fusion	24 (11)	15 (6)
Decompression	85 (35)	73 (30)
Earlier spondylodesis	19 (8)	21 (9)
Number of levels fused (median and quartiles)	2 (1; 2)	2 (1; 2)
Baseline measures		
Oswestry Disability Index	41 (36; 45)	44 (40; 48)
EuroQol EQ-5D	0.55 (0.47; 0.63)	0.56 (0.49; 0.63)

Values are percentages (number of patients) unless otherwise stated.
SD indicates standard deviation.

Use of primary health care, including contacts to general practitioners, medical specialist, and physiotherapists, was extracted from The National Health Insurance Service Register and valued using the activity-based tariffs that are used for remuneration.

Productivity costs were calculated using data on the number of weeks of sick leave obtained from a national database, the DREAM database, which is administered by the Ministry of Employment. This database includes information on all public transfer payments for all Danish citizens.[7] The productivity costs per patient were calculated using age- and sex-matched average gross salaries from Statistics Denmark (www.dst.dk).

Patients' transportation costs were calculated by the transportation distance (kilometers) multiplied by the official Danish mileage allowance. The time for transportation was estimated by assuming that 1 km of transportation took 1 minute. Time spent on rehabilitation was calculated using a fixed number

TABLE 2. Resource Use From Surgery Through 12 Months of Follow-up

Resource Use Category	6w-Group (n = 41)	12w-Group (n = 41)	Difference
Primary health care			
General practice visits	13.9 (11.2–16.6)	12.8 (10.3–15.3)	1.0 (−2.6 to 4.8)
Medical specialist visits	2.3 (1.0–3.5)	1.0 (0.4–1.6)	1.2 (−0.1 to 2.6)
Physiotherapist visits	1.8 (0.3–3.2)	4.4 (1.5–7.3)	−2.7 (−6.0 to 0.6)
Other visits	0.4 (0–1.0)	0	0.4 (−0.2–1.0)
Hospitals			
Admissions	1.5 (1.2–1.8)	1.2 (1.1–1.3)	0.3 (0.0–0.6)
Number of bed days	9.2 (7.3–11.0)	7.2 (6.0–8.5)	2.0 (−0.3 to 4.1)
Outpatient visits	8.3 (6.6–10.0)	5.3 (4.4–6.1)	3.0 (1.1–4.9)
Production loss			
Weeks of sick leave	25.2 (18.4–31.9)	24.9 (18.0–31.8)	0.3 (−9.5 to 10.0)
Patients costs			
Transportation (km)	387 (289–485)	374 (300–447)	13.0 (−110 to 137)
Hours (transportation and rehabilitation)	26.5 (24.8–28.1)	26.2 (25.0–27.5)	0.2 (−1.8 to 2.3)

Values are mean number of units per patient (95% confidence intervals).

of in accordance with the protocol. Patients' time was valued using age- and sex-matched average net salaries. Out-of-pocket costs such as medication, informal care, and aids were assessed using a modified version of the Dutch cost diary.[8] However, because of poor compliance in registering these costs, out-of-pocket costs were excluded from the main analysis.

Outcome Parameters

The primary outcome was functional disability as measured by the Oswestry Disability Index.[9,10] Furthermore, health-related quality of life was measured by the EuroQol 5-dimensions[11] and valued by Danish preference weights[12] to calculate health utility scores and quality-adjusted life years (QALY).

TABLE 3. Resource Use From Surgery Through 12 Months of Follow-up (Euro)

Cost Category	6w-Group (n = 41)	12w-Group (n = 41)	Difference
Primary health care			
General practice visits	255 (194–316)	224 (170–279)	31 (−52 to 114)
Medical specialist visits	96 (39–154)	63 (20–107)	33 (−40 to 106)
Physiotherapist visits	18 (5–31)	45 (17–73)	−27 (−59 to 5)
Other visits	6 (0–17)	0	6 (−4 to 17)
Hospitals			
Admissions	22,398 (20,519–24,276)	20,076 (18,866–21,286)	2322 (70–4574)
Outpatient visits	3029 (1254–4804)	1369 (1066–1672)	1660 (−142 to 3461)
Production loss			
Weeks of sick leave	29,233 (21,196–37,270)	25,754 (18,079–33,428)	3479 (−7679 to 14,638)
Patient's cost			
Transportation expenses	104 (77–131)	100 (81–120)	4 (−30 to 37)
Time (transportation and rehabilitation)	398 (374–421)	395 (366–424)	3 (−36 to 41)
Total cost	54,864 (46,377–63,350)	47,995 (40,146–55,842)	6869 (−4640 to 18,378)

Values are mean cost per patient (95% confidence intervals).

TABLE 4. Patient-Reported Outcomes Used in the Economic Evaluation

	6w-Group		12w-group		Difference	
	ODI	EQ-5D	ODI	EQ-5D	ODI	QALY*
Baseline						
Complete case (n = 41/41)	41 (36–45)	0.55 (0.47–0.63)	44 (40–48)	0.56 (0.49–0.63)	−3 (−9 to 3)	NA
12 mo						
Complete case (n = 33/34)	32 (27–38)	0.67 (0.60–0.74)	23 (18–28)	0.78 (0.72–0.83)	9 (1–17)	NA
Imputed (n = 41/41)	31 (26–37)	0.68 (0.60–0.74)	25 (19–29)	0.75 (0.70–0.82)	6 (1–15)	NA
Difference						
Complete case (n = 33/34)	−9 (−15 to −3)	0.11 (0.03–0.18)	−20 (−25 to −14)	0.18 (0.10–0.26)	−11 (−19 to −2)	−0.07 (−0.18 to 0.03)
Imputed (n = 41/41)	−10 (−15 to −3)	0.12 (0.05–0.19)	−18 (−25 to −14)	0.18 (0.11–0.27)	−9 (−18 to −3)	−0.04 (−0.13 to 0.01)

Values are mean scores per patient (95% confidence intervals).

**Calculation of QALY estimates were additionally based on 6 mo of follow-up (not shown).*

ODI indicates Oswestry Disability Index; EQ-5D, EuroQol 5 dimensions; QALY, Quality-adjusted life year; NA, not applicable.

Imputation of Missing Data

To handle missing data on the outcome parameters, we used the method of multiple imputation.[13] Logistic regressions were used to identify covariates of the "missingness," which were then included in the model for multiple imputation: age, sex, all EuroQol 5-dimensions and Oswestry Disability Index time points, working status at baseline and at the 1-year follow-up, 6-meter-walking test at baseline, and a log transformation of the total cost. Imputations were produced using linear regression, and sensitivity analysis was made with respect to including less (only the parameters we wanted to impute) or more covariates (all variables of our data set).

Economic Evaluation

The resource use, costs, and clinical outcomes are presented as means with 95% bootstrapped confidence intervals (95% CI). A nonparametric bootstrapping method (10,000 replicates) was used because these parameters had right-skewed distributions.[14] To assess the cost-effectiveness of the interventions, the conventional ICER (incremental cost-effectiveness ratio) was calculated using the following formula:

$$\text{ICER} = (C_A - C_B)/(E_A - E_B),$$

where C denotes costs and E denotes effects with A and B referring to comparators. The ICER is, however, undefined if the ratio or just one of the confidence limits is negative. For that reason, the parameters were transformed into net benefit in order for cost-effectiveness acceptability curves to be drawn. The curves show the probability that an intervention is cost-effective compared with its alternative for a continuum of hypothetical threshold values of willingness to pay for the outcome.[15] Sensitivity analysis was conducted by restricting the analysis to cases with complete response and with respect to the specification of the imputation model, as described in the earlier text.

RESULTS

The patients in the 2 groups were comparable at baseline in terms of age, fusion level, decompression, and outcome measures (Table 1). By random, the 6w-group included 53% male patients, whereas the 12w-group included only 42% male patients.

Service utilization is shown in Table 2 and the corresponding costs in Table 3. The 6w-group had an average of 2 extra bed days (inpatient hospital stay) than the 12w-group, though this difference was not statistically significant. The differences in bed days between the 2 groups were caused by more readmissions in the 6w-group than the 12w-group. Only 2 patients in the 6w-group and 1 patient in the 12w-group were readmitted prior to the rehabilitation. The majority of readmissions occurred between 6 and 12 months postsurgery, and were not directly associated with the patients' rehabilitation after spinal surgery. The 6w-group also had an average 0.3 extra admissions to the hospital, as well as 3 extra outpatient visits than the 12w-group, and these differences were statistically significant. The opposite was seen for physiotherapy visits in the primary health care sector where the 12w-group on average had 2.7 more contacts than the 6w-group, but this difference was not statistically significant. The average total cost per patient was €54,864 in 6w-group and €47,995 in the 12w-group, leading to a cost difference against early initiation of €6869 (95% CI, −4640 to 18,378).

Table 4 shows the difference between the groups relating to functional disability and QALY. Fifteen patients (18%) had

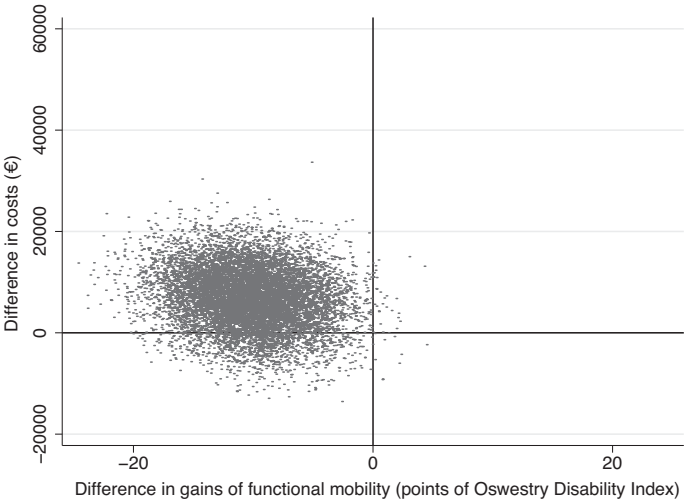

Figure 1. Consequences of early initiation of rehabilitation after lumbar spinal fusion: bootstrapped differences in costs and functional disability.

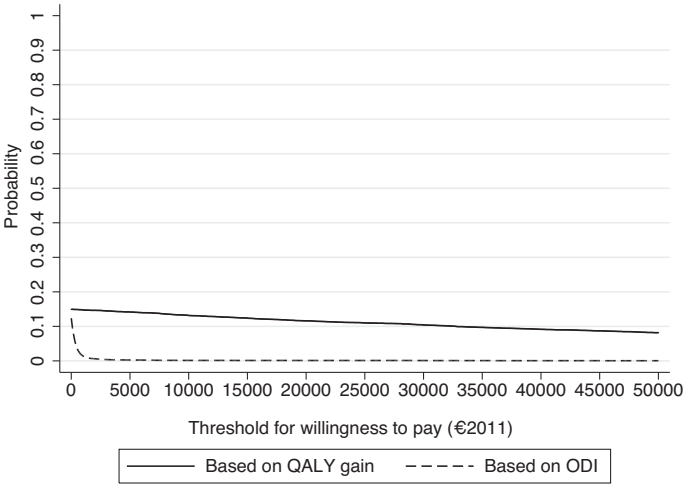

Figure 3. The probability that early initiation of rehabilitation after lumbar spinal fusion will be cost effective. QALY indicates quality-adjusted life years; ODI, Oswestry Disability Index.

not returned the questionnaires at the 1-year follow-up, and for these patients we imputed the missing data. The extent of missing data was evenly distributed between the 2 groups. It can be seen from the Table 4 that the imputation procedure lowered the average performance of both groups, as the missingness was generally correlated with lower baseline values of QALY and walking ability, as well as younger age and higher total cost. The results of both complete case analysis and analysis based on imputed data showed that the 6w-group had significantly poorer outcome in relation to functional disability than the 12w-group. The same tendency was found for QALY, although this difference was not statistically significant.

The statistical variation surrounding the results is illustrated in the cost-effectiveness planes of Figure 1 (using functional disability as outcome measure) and Figure 2 (using QALY as outcome measure). Each estimate in the plane represents a bootstrapped replication of the difference in total cost and the difference in outcomes between the 2 groups. For both figures, the replicates are primarily located in the northwest quadrant of the plane, which indicates that early rehabilitation is less effective and more costly.

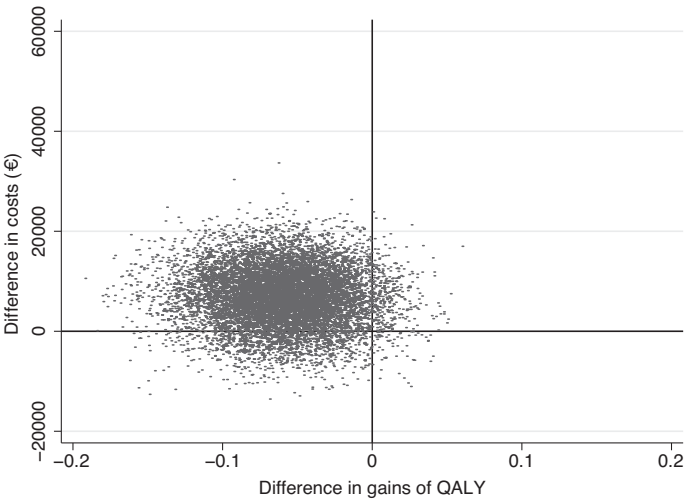

Figure 2. Consequences of early initiation of rehabilitation after lumbar spinal fusion: bootstrapped differences in costs and QALY. QALY indicates quality-adjusted life years.

Given that it is unknown how decision makers value the outcomes, the probability for cost-effectiveness is usually illustrated in cost-effectiveness curves as shown in Figure 3. The probability that early initiation is cost-effective does not exceed 15% irrespective of how much or how little decision makers are willing to pay for outcomes. It should be noted that the curves do not cut the *y*-axis at zero because the fast-track strategy falls out cost saving for about 15% of the replicates that were illustrated in the previous figures. Also, the higher we value outcomes, the more unlikely it is that early initiation of rehabilitation leads to positive net benefit.

An omitted cost category in the main analysis was patients' out-of-pocket costs other than transportation costs. This was because of low compliance in logging these costs; at the 3-month follow-up, 62% reported their costs, but this figure had dropped to 27% at the 6-month follow-up and 22% at the 1-year follow-up. Table 5 shows the mean cost per year for responders. The 6w-group on average seemed to receive less help from family and friends than the 12w-group. The total cost per patient was €2248 (95% CI, 0 to −4513) for 6w-group compared with a mean of €2881 (95% CI, 1486–4276) in the 12w-group, but these differences were not statistically significant.

The results of the sensitivity analysis for complete case analysis and alternative specifications of the imputation model supported the robustness of the main findings. The probability for cost-effectiveness changed less than 1% (in both directions) when basing the analysis on the different imputation models. Similarly, including only complete cases

TABLE 5. Patients' Out-of-Pocket Costs and Informal Caregivers' Time Costs

	6w-Group (n = 25)		12w-Group (n = 28)		Difference, Costs
	Units	Costs	Units	Costs	
Prescription medication	NA	555 (183–927)	NA	354 (112–597)	200 (−241 to 642)
Nonprescription medication	NA	11 (6–15)	NA	6 (4–8)	4 (−1 to 9)
Help from family and friends	5 (2–8)	1336 (500–2172)	10 (5–15)	2699 (1291–4106)	−1363 (−3009 to 284)
Private home care	0.3 (−0.8 to 0.2)	91 (−48 to 231)	0.01 (0–0.3)	3 (−2 to 8)	88 (−52 to 228)
Private domestic help	0.2 (0–0.5)	51 (−35 to 137)	0.2 (0–0.5)	55 (−29 to 140)	−4 (−129 to 121)
Expenses for aids	NA	1643 (−1516 to 4802)	NA	1100 (−297 to 2497)	543 (−3049 to 4135)
Total	NA	2248 (−18 to 4513)	NA	2881 (1486–4276)	−633 (−3310 to 2044)

Values are mean number of units and costs (euro) per patient (95% confidence intervals).
NA indicates not applicable.

had little impact because the probability for cost-effectiveness here dropped by 1% only.

DISCUSSION

This study reports on an economic evaluation conducted alongside a randomized controlled trial. The main findings were that initiating of rehabilitation 6 weeks after a lumbar spinal fusion as opposed to initiating rehabilitation 12 weeks postoperatively is unlikely to be cost-effective.

The tendency of inferior performance regarding functional disability has already been described.[6] This study contributes with the finding that protracted rehabilitation does not prolong the patients' recovery or return to work. The early initiation of rehabilitation did not improve the patients' overall quality of life. On the contrary, the early initiation was associated with higher use of health care services.

Strengths and Weaknesses

Although the evidence on the effect of rehabilitation has extended during recent years, no "gold standard" for the optimum rehabilitation protocol exists. To assess the additional uncertainty about the effect of timing of rehabilitation, we adapted the only protocol that has proven both clinically superior and cost-effective,[2,5] and which is the routine protocol at our centers. Alternative choices in the literature are limited to a protocol for which no cost-effectiveness evaluation has been reported,[1] and a so-called concept study evaluating several means in a study did not report cost-effectiveness.[3,16]

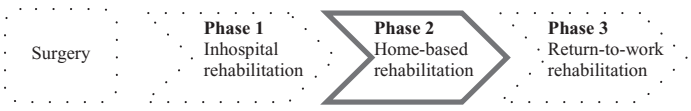

Figure 4. Phases of postsurgery rehabilitation for lumbar spinal fusion patients.

At the 1-year follow-up, 15 patients (18%) had not reported on the clinical outcome measures, whereas we had complete follow-up on the economic data. We used the method of multiple imputation to enable analysis of all patients, which is in line with recommendations of leading commentators.[13] The argumentation is that we cannot assume that the responders do validly represent the 15 nonresponders to base the analysis on simpler approaches to missing data that do not take into account that the missingness is often associated with specific patient characteristics. In a series of sensitivity analyses, we compared different imputation models and found no difference in the overall results when the different models were used. This supports the robustness of our approach in the main analysis, as does the fact that complete case analysis does not alter the conclusion.

We used several national registries to determine the use of health care services and to calculate the overall costs per patient. These registries have been found useful for research purposes.[17] The full follow-up regarding the use of health services is considered to strengthen this study. On the contrary, it turned out to be very difficult to measure the patients' out-of-pocket costs. Despite the incompleteness of their replies, we saw that relatively large costs were covered by family and friends and spent on buying aids. The 6w-group in general used €633 less than the 12w-group. Comparing this with the overall finding of an increased use in cost of €6869 within the 6w-group compared with 12w-group suggests that inclusion of the patients' out-of-pocket costs would not change the overall results of this study.

External Validity

In relation to a national context, external validity is supported by the participation of both general hospitals and a university hospital. In relation to a European or a North American context external validity is evidently a much more complex issue. Throughout the Western world, there are large structural and

cultural differences concerning the rehabilitation offer. The results of an economic evaluation are driven by several factors that are strongly correlated to the setting. Today's validated patient-based outcome measures are accepted in the Western world, and their estimates thought to be generalizable. However it should be noted that just as item costs vary across settings, so do the values (preference weights) used to calculate the QALY. Decision makers should therefore consider whether the item costs used in this analysis are generalizable to their setting, and whether cultural or structural differences could lead to different service use for the same complications and/or comorbidities. Finally, decision makers might consider whether the incentive to return to work is similar between different social systems. The fact that our results are rather strong and observed with similar signs for all parameters indicates that a similar conclusion could be expected in other Western countries.

Impact on Clinical Management

Generally, postsurgery rehabilitation after lumbar spinal fusion can be categorized according to 3 phases, as illustrated in Figure 4. Fast-track inhospital rehabilitation strategies are currently well implemented in many institutions, with the aim of speeding up the initial mobilization and decreasing bed days (Phase 1).

This study analyzes the cost-effectiveness of an early *versus* a late home-based rehabilitation strategy (Phase 2). Our study is the first to challenge the fast-track trend in home-based rehabilitation, and the evidence developed in this study shows that early initiation of rehabilitation for lumbar fusion patients is not appropriate. The study does not allow for a conclusion on the "optimum" timing of rehabilitation or on the best rehabilitation protocol. Nor does the study conclude on the impact of specific return-to-work intervention (Phase 3). Most importantly the study does document that timing has a significant impact on the cost-effectiveness of home-based rehabilitation. We recommend that these results are taken into account before any clinical implementation of new postoperative treatment strategies. Further rehabilitation research is clearly needed.

CONCLUSION

Despite the observed shift in clinical practice toward earlier rehabilitation using various fast-track strategies this study found that initiating rehabilitation 6 weeks as opposed to 12 weeks after a lumbar spinal fusion is associated with poorer outcomes and higher costs, leading to the conclusion that early initiation of rehabilitation is unlikely to be cost-effective for this patient population.

➢ Key Points

- ❑ Initiating rehabilitation 6 weeks as opposed to 12 weeks after a lumbar spinal fusion is associated with poorer outcomes and higher costs.
- ❑ The patients initiating rehabilitation early perform worse on functional mobility and gain less quality of life, but also consume more use of health care services during the first year postsurgery.
- ❑ The overall probability for early initiating of rehabilitation being cost-effective does not reach 10% at conventional thresholds for cost-effectiveness.

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